The neurophysiological effects of dry needling in patients with upper trapeizus myofascial trigger points: study protocol of a controlled clinical trial

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Abstract

Introduction: Dry needling (DN) is an effective method for the treatment of myofascial trigger points (MTrPs). There is no report on the neurophysiological effects of DN in patients with MTrPs. The aim of the present study will be to assess the immediate neurophysiological efficacy of deep DN in patients with upper trapezius MTrPs.

Methods and analysis: A prospective, controlled clinical trial is designed to include patients with upper trapezius MTrPs and volunteered healthy subjects to receive one session DN. The primary outcome measures are neuromuscular junction response (NMJR) and sympathetic skin response (SSR). The secondary outcomes are the pain intensity and the pressure pain threshold. Data will be collected at baseline and immediately after intervention.

Ethics and dissemination: This study protocol has been approved by The Research Council, School of Rehabilitation and the Ethics Committee of Tehran University of Medical Sciences. The results of the study will be disseminated in a peer-reviewed journal and presented at international congresses.

Article summary

Article focus:

- This study will evaluate the neurophysiologic as well as pain relieving effectiveness of deep dry needling (DN) in patients with upper trapezius myofascial trigger points (MTrPs).

Key messages:

This study will demonstrate the immediate effectiveness of the DN on pain, neuromuscular junction response, and autonomic responses in the upper trapezius MTrPs.

Strengths and limitations of this study:

- This clinical study will be the first controlled clinical trial to investigate the immediate neurophysiological effects of the DN on the MTrPs.
- This protocol will help to understand the mechanisms of DN for treating MTrPs.
- The major limitation is that the therapist applying intervention will be the assessor collecting the data.
- The Long term as well as functional effects will not be investigated.

Introduction

Myofascial trigger points (MTrPs) Myofascial trigger points (MTrPs), characterized as local hypersensitive points that usually form a palpable taut band within skeletal muscle fibers, are considered as a major source of pain in 30% of individuals with musculoskeletal dysfunction.[1-4] There are two categories, active or latent, trigger points that may develop within a skeletal muscle. Active trigger points are spontaneously active and produce local or referred pain to remote structures. Latent trigger points, however, are not spontaneously active and would not produce any symptoms unless being evoked by an external stimulant.[1, 5] In the upper quadrant, postural muscles in general and upper trapezius muscle in particular are most affected by MTrps.[6-8] Presence of active trigger points in a muscle may exhibit cause sensory, motor and autonomic symptoms. [1, 2]

The etiology of trigger point formation in a muscle and its mechanism of producing somatic symptoms are not fully understood. It is proposed that trigger points often form at the location of muscle endplates causing chemical changes and abnormal endplate activity at neuromuscular junction.[9,10] Continuous irritation of the endplates leads to excessive release of acetylcholine. Release of acetylcholine or lack of acetylcholinesterase results in taut band formation which are constant localized muscle fiber contraction.[10,11] Biochemical changes,[12-14] Chronic overuses or muscle injuries,[15] and Central

sensitization,[10, 16] are other factors that could lead to trigger point formation in a skeletal muscle.

Patients with MTrPs may present with autonomic symptoms including sweating, pilomotor activity, changes in skin temperature, lacrimation, and salivation[2]. The sympathetic nervous system activity may also increase motor activity and cause muscle pain at MTrPs[17-19].

Considering different causes for trigger point formation, there are a variety of invasive and noninvasive treatments proposed for managing MTrPs. Noninvasive methods used in physiotherapy include stretching, laser therapy, ultrasound, TENS, and biofeedback.[20] Dry needling (DN) is a relatively new invasive method which is increasingly used for treatment of MTrPs.[20] Dry needling involves inserting a needle into a MTrP without injecting any medication. This technique is reported to be an effective and efficient treatment for reducing somatic pain and dysfunction associated with MTrP in a muscle.[20-22] There is no study investigating the effect of DN on neuromuscular junction response and autonomic responses in a population with MTrPs.

Aims and Objectives

The aim of the present study will be to investigate the effects of DN on neuromuscular junction response and sympathetic outflow in patients with MTrPs.

Methods

Study design

This study is a controlled clinical trial designed to investigate the effectiveness of dry needling on neuromuscular junction response and sympathetic outflow in patients with upper trapeizus MTrPs compared with healthy individual matched group.

Setting

The study will be performed at the Department of Electrophysiology, School of Rehabilitation, Tehran University of Medical Sciences (TUMS).

Approval of study protocol

This study has been approved by the Research Council, School of Rehabilitation, TUMS and Ethical approval has been obtained by Ethics Committee of TUMS (Reference number 2185)

Informed consent

Written informed consent will be obtained from all patients. We will provide patients with information about the detail of the project. Patients will be free to withdraw from the study at any time.

Participants

Patients will be recruited from the university orthopedic and physiotherapy clinics at the TUMS. To be included in the study, patients have to be aged between 20 and 40 years old and to have upper trapezius active MTrPs. The three important criteria for diagnosing MTrPs will be: 1) taut band, 2) tender point in a taut band, 3) recognition of pain. Patients with a history of spinal or shoulder disorders, neck and upper extremity surgery, acute disease, muscle diseases, neurological or systemic disorder (such as lupus erythematus, scleroderma), epilepsy, pregnancy, using sedative drugs, needle phobia, bleeding disorder, anticoagulant medication, previous experience with dry needling for myofascial pain, Skin lesion and infection or inflammatory oedema at MTrPs site will be excluded.

Outcome measures

The outcome measures will be the Neuromuscular Junction Response (NMJR), Sympathetic Skin Response (SSR), Pain Intensity, and Pressure Pain Threshold (PPT), which will be taken and recorded before and immediately after dry needling treatment. All measurements will be done by one trained physiotherapist between 9 to 12 a.m.

Primary outcome measures

Neuromuscular Junction Response (NMJR)

Electrodignostic technique of repetitive nerve stimulation (RNS) for assessing NMJR will be used, which is the most widely used method in the evaluation of NMJR. The RNS method is based on repetitive supramaximal stimulation and the measurement of decremental/incremental responses. The amplitude of the evoked trapezius compound muscle action potential (CMAP) will be measured. Recording will be made with surface electrodes with the patient in supine on an examination table (sensitivity 5 mV//Div; sweep speed 5 msec /Div; filtering of 5 Hz - 5 KHz). Surface stimulating electrodes will be placed over the spinal accessory motor nerve along the posterior border of the sternocleidomastoid muscle at the level of upper border of thyroid cartilage. The active electrode will be placed on the skin over the upper trapezius muscle 5 cm from the C7 spinous process, and the reference electrode will be located 2 cm from the C7 spinous process. Trains of 9 supramaximal electrical stimulation at a rate of 3 Hz will be delivered to the spinal accessory nerve, and the evoked trapezius CMAP will be recorded. The ratio of the amplitudes of the fifth to the first responses will be used as a measure of decrement or increment expressed as a percentage. Trapezius skin temperature will be measured.

Sympathetic Skin Response (SSR)

Tonnies electromyography instrument (Neuroscrteen Plus- Germany) with surface electrodes to assess SSR (sensitivity 500 micV/Div; sweep speed 1000 msec/Div; filtering of 0.08 Hz – 20 Hz) will be used to assess changes in SSR. The measurements will be carried out in a silent, semidark room with patients in a supine position and their eyes closed. Care will be taken to maintain a comfortable room temperature of 24.0 °C. The SSR will be recorded following a single square-wave electric stimulus over the median nerve at the wrist. The recording and reference electrodes will be placed on the palm, and on the back of the hand, respectively. Three electrical stimulations with 1 minute interval will be delivered. Patients will be asked to remain calm throughout the procedure. The mean of 3 trials will be obtained. The SSR latency, duration, and amplitude will be calculated to assess the sympathetic function.

Secondary outcome measures

Pain Intensity

Pain intensity will be self rated by subjects on a 0-10 numerical rating scale with 0 representing no pain and 10 representing the worst imaginable pain.

Pressure Pain Threshold (PPT)

The physiotherapist will use a pressure algometer (Digital Instrument-Lutron, Taiwan) to measure the pressure pain threshold. First, the whole

procedure will be explained to the subjects. To measure PPT, subject will be placed in a comfortable supine position and the most painful spot in the upper trapezius MTrP region will be identified. Then, the metal rod of algometer will be pressed perpendicular to the skin over the identified trigger points in the upper trapezius muscle. The applied pressure will be increased in the rate of 1 kg/cm^2.The participant in the control group will be asked to say "yes" as soon as they feel pain or discomfort. Subjects in the treatment group will require to report when they experienced an increase in pain intensity or discomfort (for MTrPs group). This procedure will be repeated 3 times with 40 sec intervals. The average of 3 values will be determined as the PPT.

Intervention

Following baseline measurements, deep DN will be provided by a licensed and trained physiotherapist. Participants in both groups will receive one session of DN treatment for the trapezius muscle. Participants will be placed in a supine position on the examination table. The sterile acupuncture needles of 0.30 mm diameter and 50 mm long will be used (Seirin, J Japan). The needle will be inserted into the skin over the palpated trigger point and will be slowly advanced until it reaches the trigger point and a twitch response is elicited. Reproduction of identifiable pain or visualization of a local twitch response indicates appropriate needle placement[23]. Each trigger point will be repeatedly needled for 1 – 2 minutes until the pain is resolved.

Sample size

As there is no a related study to estimate the effect size, sample size with an alpha of 0.05 and a beta level of 0.8 will be determined by using a pilot data.

Procedures

Patients will be recruited for voluntary participation in the study from the pool of patients with shoulder and neck pain at the TUMS orthopedics and physiotherapy clinics. Volunteers matched in age, gender, body mass index with no history of current neck and shoulder pain will be recruited for the control group. All interested participants will receive verbal and written explanation of the goals and procedures of the study and will be asked to sign a written consent form for their voluntary participation. The same physiotherapist who provides DN treatment will collect the pre and post treatment data from each subject.

Statistical Analysis

Data analysis will be performed using the SPSS (version 17) software. Means, standard deviations and 95% CIs will be calculated for all outcome measures. kolmogorof-smirnov test will be performed to determine if the data have normal distribution. If the dataset distribute normally, parametric test of Multivariate Analysis of Variance (MANOVA) will be used to compare the outcomes between the treatment and control groups. If normality is not established, then non-parametric test Mann-Whitney U will be used for data analysis. p-value of < 0.05 will be considered statistically significant.

Results

Demographic characteristics of participants will be illustrated in table1.

Table 1 about here

Descriptive statistics associated with each outcome measure obtained from both groups will be presented in table2.

Table 2 about here

Discussion

The present study, will investigate the effects of DDN on the NMJR and SSR in patients with active MTrPs in their upper trapezius muscle. To the best of our knowlage this study will be the first report evaluating the immediate effect of the DDN on SSR, NMJR and pain in muscles with and without MTrPs. Authors of this study will explain the findings of this study and will discuss how they relate to the current hypothesis which attributes development of the MTrPs in the skeletal muscles to excessive acetylcholine release in the neuromuscular junction (NMJ), sarcomere shortening, and abnormal release of sensitizing substances.[12, 13, 24] The authors will discuss how the findings of this study will advance our understanding of mechanisms underlying MTrPs formation in the skeletal muscles and will assist in exploring potential effective and efficient treatments for patients. Authors will also discuss the mechanism of pain reduction through DN and how it might relate to the Mezack's Gate

Control Theory [25, 26]. In this study, possible relationship between improvement of pain intensity and PPT following DN and the rule of changes in NMJR and SSR will be discussed.

Limitation

Although desired, but due to technical difficulties, the assessing therapist will not be blinded to the subject's group assignment. Another limitation of the study will be lack of functional measures to investigate long term effects of DDN on subjects' functional abilities.

Conclusions

The results of the present study will show the effects of DN on neuromuscular junction response and autonomic response in patients with upper trapezius MTrPs.

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Contributors: All authors contributed to the study conception and the design. MA is the principal investigator and will responsible for dry needling and collecting data. MA together with NNA will perform the statistical analyses. All authors will contribute to the interpretation of the study results. MA wrote the manuscript for publication. NNA read and revised the manuscript critically for important intellectual content. All authors reviewed the final manuscript and gave approval of the manuscript.

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Competing interests: None.

Provenance and peer review: Not commissioned; externally peer reviewed.

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Table 1: Demographic and clinical characteristics of study participants

	Number	Mean ±SD (range)	Minimum	Maximum
Gender M F				
Age (years)				
Weight (Kg)				
Height (cm)				
BMI ($Kg/m^{2)}$				
Duration of illness (Month)				
Affected side R L				

M/F, Male/Female; BMI, Body Mass Index; R/L, Right/Left

Table 2: The results of clinical and neurophysiological measurements

	Patients		Healthy Subjects	
	Before DN	After DN	Before DN	After DN
	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)
SSR Latency (ms)				
SSR Amplitude (μv)				
SSR Duration (ms)				
NMJR (% change)				
Pain intensity				
PPT ($kg/cm^{2)}$				

PPT, Pressure Pain Threshold; SSR, Sympathetic Skin Response; NMJR, Neuromuscular Junction Response; DN, Dry Needling

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Methods and analysis: A prospective, controlled clinical trial is designed to include patients with upper trapezius MTrPs and volunteered healthy subjects to receive one session DN. The primary outcome measures are neuromuscular junction response (NMJR) and sympathetic skin response (SSR). The secondary outcomes are the pain intensity and the pressure pain threshold. Data will be collected at baseline and immediately after intervention.

Ethics and dissemination: This study protocol has been approved by The Research Council, School of Rehabilitation and the Ethics Committee of Tehran University of Medical Sciences. The results of the study will be disseminated in a peer-reviewed journal and presented at international congresses.

Article summary

Article focus:

- This study will evaluate the neurophysiologic as well as pain relieving effectiveness of deep dry needling (DN) in patients with upper trapezius myofascial trigger points (MTrPs).

Key messages:

This study will demonstrate the immediate effectiveness of the DN on pain, neuromuscular junction response, and autonomic responses in the upper trapezius MTrPs.

Strengths and limitations of this study:

- This clinical study will be the first controlled clinical trial to investigate the immediate neurophysiological effects of the DN on the MTrPs.
- This protocol will help to understand the mechanisms of DN for treating MTrPs.
- The major limitation is that the therapist applying intervention will be the assessor collecting the data.
- The Long term as well as functional effects will not be investigated.

Introduction

Myofascial trigger points (MTrPs), characterized as local hypersensitive points that usually form a palpable taut band within skeletal muscle fibers, are considered as a major source of pain in 30% of individuals with musculoskeletal dysfunction.[1-4] There are two categories, active or latent, trigger points that may develop within a skeletal muscle. Active trigger points are spontaneously active and produce local or referred pain to remote structures. Latent trigger points, however, are not spontaneously active and would not produce any symptoms unless being evoked by an external stimulant.[1, 5] In the upper quadrant, postural muscles in general and upper trapezius muscle in particular are most affected by MTrps.[6-8] Presence of active trigger points in a muscle may exhibit cause sensory, motor and autonomic symptoms. [1, 2]

The etiology of trigger point formation in a muscle and its mechanism of producing somatic symptoms are not fully understood. It is proposed that trigger points often form at the location of muscle endplates causing chemical changes and abnormal endplate activity at neuromuscular junction.[9,10] Continuous irritation of the endplates leads to excessive release of acetylcholine. Release of acetylcholine or lack of acetylcholinesterase results in taut band formation which are constant localized muscle fiber contraction.[10,11] Biochemical changes,[12-14] Chronic overuses or muscle injuries,[15] and Central sensitization,[10, 16] are other factors that could lead to trigger point formation in a skeletal muscle.

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Considering different causes for trigger point formation, there are a variety of invasive and noninvasive treatments proposed for managing MTrPs. Noninvasive methods used in physiotherapy include stretching, laser therapy, ultrasound, Transcutaneous Electrical Nerve Stimulation (TENS), and biofeedback.[20] Dry needling (DN) is a relatively new invasive method which is increasingly used for treatment of MTrPs.[20] Dry needling involves inserting a needle into a MTrP without injecting any medication. This technique is reported to be an effective and efficient treatment for reducing somatic pain and dysfunction associated with MTrP in a muscle.[20-22] There is no study investigating the effect of DN on neuromuscular junction response (NMJR) and autonomic responses in a population with MTrPs. Therefore, for safe practice of DN, it is important to study the neurophysiological responses to DN in subjects with MTrPs compared to healthy individuals. We hypothesized that 1) Subjects with MTrPs will show irregular NMJR compared to individuals without, 2) DN will result in a higher sympathetic response in subjects with MTrPs compared to healthy individuals, 3) DN will normalize neuromuscular junction responses in subjects with MTrPs

Aims and Objectives

The aim of the present study will be to investigate the effects of DN on neuromuscular junction response and sympathetic outflow in individuals with MTrPs.

Methods

Study design

This study is a controlled clinical trial designed to investigate the effectiveness of dry needling on neuromuscular junction response and sympathetic outflow in patients with upper trapeizus MTrPs compared with healthy individual matched group.

Setting

The study will be performed at the Department of Electrophysiology, School of Rehabilitation, Tehran University of Medical Sciences (TUMS), Iran.

Approval of study protocol

This study has been approved by the Research Council, School of Rehabilitation, TUMS and Ethical approval has been obtained by Ethics Committee of TUMS (Reference number 2185).

Informed consent

A detailed description of all examination and treatment procedures, including DN, and risks involved in this study will be provided to the participants. A written informed consent will be obtained from all subjects, who agree to take part in this study, before data collection. Subjects will have the right to refuse DN treatment and withdraw from the study at any time without penalty. The same physiotherapist as is administering the intervention will obtain it.

Participants

Patients will be recruited from the university orthopedic and physiotherapy clinics at the TUMS. To be included in the study, patients have to be aged between 20 and 40 years old and to have upper trapezius active MTrPs. The three important criteria for diagnosing MTrPs will be: 1) taut band, 2) tender point in a taut band, 3) recognition of pain. Patients with a history of spinal or shoulder disorders, neck and upper extremity surgery, acute disease, muscle diseases, neurological or systemic disorder (such as lupus erythematus, scleroderma), epilepsy, pregnancy, using sedative drugs, needle phobia, bleeding disorder, anticoagulant medication, previous experience with dry needling for myofascial pain, Skin lesion and infection or inflammatory oedema at MTrPs site will be excluded.

Recruitment

Volunteers for participation in this study will be recruited from the pool of patients diagnosed with myofascial related shoulder or neck pain at the TUMS orthopedics and physiotherapy clinics. Subjects are informed about the purpose of the study and the examination and treatment procedures involved in this project. Patients will have the option of participating in this study or continuing with the regular care through the clinic. Healthy volunteers matched in age, gender, body mass index with no history of current neck and shoulder pain will be recruited through advertisements on bulletin boards, posting flyers or verbal requests in the above mentioned clinics and rehabilitation department at TUMS. The same physiotherapist who provides DN treatment will collect the pre and post treatment data from each subject.

Outcome measures

The outcome measures will be the Neuromuscular Junction Response (NMJR), Sympathetic Skin Response (SSR), Pain Intensity, and Pressure Pain Threshold (PPT), which will be taken and recorded before and immediately after dry needling treatment. All measurements will be done by one trained physiotherapist between 9 to 12 a.m.

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Pain Intensity

Pain intensity will be self rated by subjects on a 0-10 numerical rating scale with 0 representing no pain and 10 representing the worst imaginable pain.

Pressure Pain Threshold (PPT)

The physiotherapist will use a pressure algometer (Digital Instrument-Lutron, Taiwan) to measure the pressure pain threshold. First, the whole

procedure will be explained to the subjects. To measure PPT, subject will be placed in a comfortable supine position and the most painful spot in the upper trapezius MTrP region will be identified. Then, the metal rod of algometer will be pressed perpendicular to the skin over the identified trigger points in the upper trapezius muscle. The applied pressure will be increased in the rate of 1 kg/cm^2.The participant in the control group will be asked to say "yes" as soon as they feel pain or discomfort. Subjects in the treatment group will require to report when they experienced an increase in pain intensity or discomfort (for MTrPs group). This procedure will be repeated 3 times with 40 sec intervals. The average of 3 values will be determined as the PPT.

Intervention

Following baseline measurements, deep DN will be provided by a licensed and trained physiotherapist. Participants in both groups will receive one session of DN treatment for the trapezius muscle. Participants will be placed in a supine position on the examination table. The sterile acupuncture needles of 0.30 mm diameter and 50 mm long will be used (Seirin, J Japan). The needle will be inserted into the skin over the palpated trigger point and will be slowly advanced until it reaches the trigger point and a twitch response is elicited. Reproduction of identifiable pain or visualization of a local twitch response indicates appropriate needle placement[23]. Each trigger point will be

repeatedly needled for 1 – 2 minutes until the pain is resolved. No concomitant medications or therapies will be allowed.

Adverse effects

Dry needling has been used safely for treating MTrPs in patients with myofascial related pain and dysfunction. However, being a minimally invasive treatment, there are some risks involved in this procedure. There are minimal chances of infection, local bleeding, increased pain and stiffness and a rare chance of induced pneumothorax with needing. Using single-rapped-sterilized needles will significantly reduce the chance of infection. Monitoring patient's history and excluding patients with cardiovascular and bleeding problems or those who are taking blood thinner medications will reduce the chance of bleeding. Providing treatment by an experienced and trained physiotherapist and following the recommended procedures for safe needling of the trapezius muscle will reduce the chance of pneumothorax. Participants may experience local muscle soreness after needling. This side effect is not usually significant. Nevertheless, the needle insertion site will be heat compressed, if necessary.

Sample size

As there is no a related study to estimate the effect size for primary outcome measures, we will conduct a pilot study to estimate the effect size of dry needling. Then, using power analysis the required sample size with an alpha of 0.05 and a power of 0.8 will be determined. Assuming a large effect size, we anticipate recruiting a total of 30 participants (15 in each group) for the

study. The enrollment will be continued to reach the required sample size.

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Data analysis will be performed using the SPSS (version 17) software. Means, standard deviations and 95% CIs will be calculated for all outcome measures. kolmogorof-smirnov test will be performed to determine if the data have normal distribution. If the dataset distribute normally, parametric test of Multivariate Analysis of Variance (MANOVA) will be used to compare the outcomes between the treatment and control groups. If normality is not established, then non-parametric test Mann-Whitney U will be used for data analysis. p-value of < 0.05 will be considered statistically significant. Data will be analyzed at the conclusion of data collection by a statistician who is blinded to the group assignments of the study.

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Demographic characteristics of participants will be illustrated in table1.

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The present study, will investigate the effects of DDN on the NMJR and SSR in patients with active MTrPs in their upper trapezius muscle. To the best of our knowlage this study will be the first report evaluating the immediate effect of the DDN on SSR, NMJR and pain in muscles with and without MTrPs. Authors of this study will explain the findings of this study and will discuss how they relate to the current hypothesis which attributes development of the MTrPs in the skeletal muscles to excessive acetylcholine release in the neuromuscular junction (NMJ), sarcomere shortening, and abnormal release of sensitizing substances.[12, 13, 24] The authors will discuss how the findings of this study will advance our understanding of mechanisms underlying MTrPs formation in the skeletal muscles and will assist in exploring potential effective and efficient treatments for patients. Authors will also discuss the mechanism of pain reduction through DN and how it might relate to the Mezack's Gate Control Theory [25, 26]. In this study, possible relationship between improvement of pain intensity and PPT following DN and the rule of changes in NMJR and SSR will be discussed.

Limitation

Although desired, but due to technical difficulties, the assessing therapist will not be blinded to the subject's group assignment. Another limitation of the

study will be lack of functional measures to investigate long term effects of DDN on subjects' functional abilities.

Conclusions

The results of the present study will show the effects of DN on neuromuscular junction response and autonomic response in patients with upper trapezius MTrPs.

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Contributors: All authors contributed to the study conception and the design. MA is the principal investigator and will responsible for dry needling and collecting data. MA together with NNA will perform the statistical analyses. All authors will contribute to the interpretation of the study results. MA wrote the manuscript for publication. NNA read and revised the manuscript critically for important intellectual content. All authors reviewed the final manuscript and gave approval of the manuscript.

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Table 1: Demographic and clinical characteristics of study participants

	Number	Mean ±SD (range)	Minimum	Maximum
Gender M F				
Age (years)				
Weight (Kg)				
Height (cm)				
BMI (Kg/m$^{2)}$				
Duration of illness (Month)				
Affected side R L				

M/F, Male/Female; BMI, Body Mass Index; R/L, Right/Left

Table 2: The results of clinical and neurophysiological measurements

	Patients		Healthy Subjects	
	Before DN	After DN	Before DN	After DN
	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)
SSR Latency (ms)				
SSR Amplitude (μv)				
SSR Duration (ms)				
NMJR (% change)				
Pain intensity				
PPT ($kg/cm^{2)}$				

PPT, Pressure Pain Threshold; SSR, Sympathetic Skin Response; NMJR, Neuromuscular Junction Response; DN, Dry Needling

The neurophysiological effects of dry needling in patients with upper trapeizus myofascial trigger points: study protocol of a controlled clinical trial

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Abstract

Introduction: Dry needling (DN) is an effective method for the treatment of myofascial trigger points (MTrPs). There is no report on the neurophysiological effects of DN in patients with MTrPs. The aim of the present study will be to assess the immediate neurophysiological efficacy of deep DN in patients with upper trapezius MTrPs.

Methods and analysis: A prospective, controlled clinical trial is designed to include patients with upper trapezius MTrPs and volunteered healthy subjects to receive one session DN. The primary outcome measures are neuromuscular junction response (NMJR) and sympathetic skin response (SSR). The secondary outcomes are the pain intensity and the pressure pain threshold. Data will be collected at baseline and immediately after intervention.

Ethics and dissemination: This study protocol has been approved by The Research Council, School of Rehabilitation and the Ethics Committee of Tehran University of Medical Sciences. The results of the study will be disseminated in a peer-reviewed journal and presented at international congresses.

Article summary

Article focus:

- This study will evaluate the neurophysiologic as well as pain relieving effectiveness of deep dry needling (DN) in patients with upper trapezius myofascial trigger points (MTrPs).

Key messages:

This study will demonstrate the immediate effectiveness of the DN on pain, neuromuscular junction response, and autonomic responses in the upper trapezius MTrPs.

Strengths and limitations of this study:

- This clinical study will be the first controlled clinical trial to investigate the immediate neurophysiological effects of the DN on the MTrPs.
- This protocol will help to understand the mechanisms of DN for treating MTrPs.
- The major limitation is that the therapist applying intervention will be the assessor collecting the data.
- The Long term as well as functional effects will not be investigated.

Introduction

Myofascial trigger points (MTrPs), characterized as local hypersensitive points that usually form a palpable taut band within skeletal muscle fibers, are considered as a major source of pain in 30% of individuals with musculoskeletal dysfunction.[1-4] There are two categories, active or latent, trigger points that may develop within a skeletal muscle. Active trigger points are spontaneously active and produce local or referred pain to remote structures. Latent trigger points, however, are not spontaneously active and would not produce any symptoms unless being evoked by an external stimulant.[1, 5] In the upper quadrant, postural muscles in general and upper trapezius muscle in particular are most affected by MTrps.[6-8] Presence of active trigger points in a muscle may exhibit cause sensory, motor and autonomic symptoms. [1, 2]

The etiology of trigger point formation in a muscle and its mechanism of producing somatic symptoms are not fully understood. It is proposed that trigger points often form at the location of muscle endplates causing chemical changes and abnormal endplate activity at neuromuscular junction.[9,10] Continuous irritation of the endplates leads to excessive release of acetylcholine. Release of acetylcholine or lack of acetylcholinesterase results in taut band formation which are constant localized muscle fiber contraction.[10,11] Biochemical changes,[12-14] Chronic overuses or muscle injuries,[15] and Central sensitization,[10, 16] are other factors that could lead to trigger point formation in a skeletal muscle.

Patients with MTrPs may present with autonomic symptoms including sweating, pilomotor activity, changes in skin temperature, lacrimation, and salivation[2]. The sympathetic nervous system activity may also increase motor activity and cause muscle pain at MTrPs[17-19].

Considering different causes for trigger point formation, there are a variety of invasive and noninvasive treatments proposed for managing MTrPs. Noninvasive methods used in physiotherapy include stretching, laser therapy, ultrasound, Transcutaneous Electrical Nerve Stimulation (TENS), and biofeedback.[20] Dry needling (DN) is a relatively new invasive method which is increasingly used for treatment of MTrPs.[20] Dry needling involves inserting a needle into a MTrP without injecting any medication. This technique is reported to be an effective and efficient treatment for reducing somatic pain and dysfunction associated with MTrP in a muscle.[20-22] There is no study investigating the effect of DN on neuromuscular junction response (NMJR) and autonomic responses in a population with MTrPs. Therefore, for safe practice of DN, it is important to study the neurophysiological responses to DN in subjects with MTrPs compared to healthy individuals. We hypothesized that 1) Subjects with MTrPs will show irregular NMJR compared to individuals without, 2) DN will result in a higher sympathetic response in subjects with MTrPs compared to healthy individuals, 3) DN will normalize neuromuscular junction responses in subjects with MTrPs

Aims and Objectives

The aim of the present study will be to investigate the effects of DN on neuromuscular junction response and sympathetic outflow in individuals with MTrPs.

Methods

Study design

This study is a controlled clinical trial designed to investigate the effectiveness of dry needling on neuromuscular junction response and sympathetic outflow in patients with upper trapeizus MTrPs compared with healthy individual matched group.

Setting

The study will be performed at the Department of Electrophysiology, School of Rehabilitation, Tehran University of Medical Sciences (TUMS), Iran.

Approval of study protocol

This study has been approved by the Research Council, School of Rehabilitation, TUMS and Ethical approval has been obtained by Ethics Committee of TUMS (Reference number 2185).

Informed consent

A detailed description of all examination and treatment procedures, including DN, and risks involved in this study will be provided to the participants. A written informed consent will be obtained from all subjects, who agree to take part in this study, before data collection. Subjects will have the right to refuse DN treatment and withdraw from the study at any time without penalty. The same physiotherapist as is administering the intervention will obtain it.

Participants

Patients will be recruited from the university orthopedic and physiotherapy clinics at the TUMS. To be included in the study, patients have to be aged between 20 and 40 years old and to have upper trapezius active MTrPs. The three important criteria for diagnosing MTrPs will be: 1) taut band, 2) tender point in a taut band, 3) recognition of pain. Patients with a history of spinal or shoulder disorders, neck and upper extremity surgery, acute disease, muscle diseases, neurological or systemic disorder (such as lupus erythematus, scleroderma), epilepsy, pregnancy, using sedative drugs, needle phobia, bleeding disorder, anticoagulant medication, previous experience with dry needling for myofascial pain, Skin lesion and infection or inflammatory oedema at MTrPs site will be excluded.

Recruitment

Volunteers for participation in this study will be recruited from the pool of patients diagnosed with myofascial related shoulder or neck pain at the TUMS orthopedics and physiotherapy clinics. Subjects are informed about the purpose of the study and the examination and treatment procedures involved in this project. Patients will have the option of participating in this study or continuing with the regular care through the clinic. Healthy volunteers matched in age, gender, body mass index with no history of current neck and shoulder pain will be recruited through advertisements on bulletin boards, posting flyers or verbal requests in the above mentioned clinics and rehabilitation department at TUMS. The same physiotherapist who provides DN treatment will collect the pre and post treatment data from each subject.

Outcome measures

The outcome measures will be the Neuromuscular Junction Response (NMJR), Sympathetic Skin Response (SSR), Pain Intensity, and Pressure Pain Threshold (PPT), which will be taken and recorded before and immediately after dry needling treatment. All measurements will be done by one trained physiotherapist between 9 to 12 a.m.

Primary outcome measures

Neuromuscular Junction Response (NMJR)

Electrodignostic technique of repetitive nerve stimulation (RNS) for assessing NMJR will be used, which is the most widely used method in the evaluation of NMJR. The RNS method is based on repetitive supramaximal stimulation and the measurement of decremental/incremental responses. The amplitude of the evoked trapezius compound muscle action potential (CMAP) will be measured. Recording will be made with surface electrodes with the patient in supine on an examination table (sensitivity 5 mV//Div; sweep speed 5 msec /Div; filtering of 5 Hz - 5 KHz). Surface stimulating electrodes will be placed over the spinal accessory motor nerve along the posterior border of the sternocleidomastoid muscle at the level of upper border of thyroid cartilage. The active electrode will be placed on the skin over the upper trapezius muscle 5 cm from the C7 spinous process, and the reference electrode will be located 2 cm from the C7 spinous process. Trains of 9 supramaximal electrical stimulation at a rate of 3 Hz will be delivered to the spinal accessory nerve, and the evoked trapezius CMAP will be recorded. The ratio of the amplitudes of the fifth to the first responses will be used as a measure of decrement or increment expressed as a percentage. Trapezius skin temperature will be measured.

Sympathetic Skin Response (SSR)

Tonnies electromyography instrument (Neuroscrteen Plus- Germany) with surface electrodes to assess SSR (sensitivity 500 micV/Div; sweep speed 1000 msec/Div; filtering of 0.08 Hz – 20 Hz) will be used to assess changes in SSR. The measurements will be carried out in a silent, semidark room with patients in a supine position and their eyes closed. Care will be taken to maintain a comfortable room temperature of 24.0 °C. The SSR will be recorded following a single square-wave electric stimulus over the median nerve at the wrist. The recording and reference electrodes will be placed on the palm, and on the back of the hand, respectively. Three electrical stimulations with 1 minute interval will be delivered. Patients will be asked to remain calm throughout the procedure. The mean of 3 trials will be obtained. The SSR latency, duration, and amplitude will be calculated to assess the sympathetic function.

Secondary outcome measures

Pain Intensity

Pain intensity will be self rated by subjects on a 0-10 numerical rating scale with 0 representing no pain and 10 representing the worst imaginable pain.

Pressure Pain Threshold (PPT)

The physiotherapist will use a pressure algometer (Digital Instrument-Lutron, Taiwan) to measure the pressure pain threshold. First, the whole

procedure will be explained to the subjects. To measure PPT, subject will be placed in a comfortable supine position and the most painful spot in the upper trapezius MTrP region will be identified. Then, the metal rod of algometer will be pressed perpendicular to the skin over the identified trigger points in the upper trapezius muscle. The applied pressure will be increased in the rate of 1 kg/cm^2.The participant in the control group will be asked to say "yes" as soon as they feel pain or discomfort. Subjects in the treatment group will require to report when they experienced an increase in pain intensity or discomfort (for MTrPs group). This procedure will be repeated 3 times with 40 sec intervals. The average of 3 values will be determined as the PPT.

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Affected side R L				

M/F, Male/Female; BMI, Body Mass Index; R/L, Right/Left

Table 2: The results of clinical and neurophysiological measurements

	Patients		Healthy Subjects	
	Before DN	After DN	Before DN	After DN
	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)	Mean ± SD (Range)
SSR Latency (ms)				
SSR Amplitude (μv)				
SSR Duration (ms)				
NMJR (% change)				
Pain intensity				
PPT ($kg/cm^{2)}$				

PPT, Pressure Pain Threshold; SSR, Sympathetic Skin Response; NMJR, Neuromuscular Junction Response; DN, Dry Needling